



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/529,622

03/30/2005

John D. Cleary

11636N/1550US

1994

32885 7590 03/15/2010

STITES & HARBISON PLLC
401 COMMERCE STREET
SUITE 800
NASHVILLE, TN 37219

EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

03/15/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

richard.myers@stites.com
francine.vanaelst@stites.com

Office Action Summary	Application No. 10/529,622	Applicant(s) CLEARY ET AL.	
	Examiner Elli Peselev	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 17-30 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-21 is/are allowed.
- 6) ☒ Claim(s) 1,4-6,17,18,22 and 24-30 is/are rejected.
- 7) ☒ Claim(s) 3,8 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1623

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-6, 17, 18, 22 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lopez-Berestein et al (U.S. Patent No. 4,663,167) in view of Michel et al (U.S. Patent No. 4,902,789) or Tang (U.S. Patent No. 4,308,375).

Lopez-Berestein et al disclose a method of treating fungal infections with a composition comprising amphotericin B but do not disclose purification of amphotericin B. However, since purification of amphotericin B was well known in the art at the time of the claimed invention as disclosed by Michel et al or Tang, it would have been prima facie obvious to a person having ordinary skill in the art at the time of the claimed invention to use amphotericin B purified by a method disclosed by Michel et al or Tang in the method of treating fungal infections.

Applicant's arguments filed November 6, 2009 have been fully considered but they are not persuasive.

Applicant contends that the usefulness of USP amphotericin B has been compromised by a high incidence of adverse effects. Applicant also contends that methods disclosed by Michel et al or Tang do not produce amphotericin B having the claimed purity. These arguments have not been found persuasive. Claims 1, 4, 5 and 17 read on a composition wherein Amphotericin B is present in an amount greater than about 92%. The terminology "about 92%" encompasses an amount which is less than 92%. In the second declaration by Kramer, it is stated on page 5 that Amphotericin B, USP grade has an apparent purity of 90.4% and Amphotericin B obtained by Michel et al has an apparent purity of 91.0%. The range which is encompassed by the term "about" has not been defined in the specification. Therefore, "about 92%" is seen to include 90.4% or 91.0% i.e. the claimed purity encompasses or is very close to the purity of the prior art products.

Claims 6, 18, 22, 24, 27 and 28 read on a composition comprising an active ingredient that has at least 92% of an amphotericin B compound. In the first declaration by Kramer it is stated that the parent USP-grade amphotericin B has an apparent purity of 93%. The amount of at least 92% encompasses purity of 93% of the prior art's product.

Claim 25 reads on amphotericin B being present in an amount greater than about 96%. In the first declaration by Kramer it is stated that the product obtained by the prior

Art Unit: 1623

art's recrystallization method has an apparent purity of 95%. The term "about 96%" encompasses values below 96% such 95%.

Claims 26 and 30 read on amphotericin B being present in an amount greater than about 94%. The term "about 94%" encompasses 93% and 95% purity of the prior art's products.

Claim 29 encompasses amphotericin B being present in an amount of at least 94% which reads on 95% purity of the prior art's product.

The declaration by Cleary states that that the nominal purity of the active ingredient is defined to be 95% AmB and that the apparent purity varied between 96% and 99%. The article by Cleary et al also is directed to AmB compounds having purity of 95% or greater. However, note that the rejected claims encompass AmB having purity of less than 95%. With respect to these claims applicant's arguments have not been found persuasive for the reasons set forth above.

Claims 3, 8 are 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 19-21 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1623

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

Application/Control Number: 10/529,622

Page 6

Art Unit: 1623

/Elli Peselev/

Primary Examiner, Art Unit 1623